AF/1619

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WASHINGTON, D.C. 20231

RE: Serial No.: 09/468,777
Applicant: Keiko HASEBE, et al.
Filing Date: DECEMBER 21, 1999
For: AMPHIPATIC LIPID DISPERSION
Group Art Unit: 1619
Examiner: WELLS, L.

SIR:

Attached hereto for filing are the following papers:

"RESPONSE UNDER 37 CFR 1.116–
EXPEDITED PROCEDURE EXAMINING
GROUP 1619

RESPONSE AND REQUEST FOR RECONSIDERATION

Our check in the amount of $ -0- is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. §1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. §1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

Keiko HASEBE, et al. : EXAMINER: WELLS

SERIAL NO.: 09/468,777 : GROUP ART UNIT: 1619

FILED: DECEMBER 21, 1999 :

FOR: AMPHIPATIC LIPID DISPERSION :

#9 N.E.
9-18-01

*RESPONSE UNDER 37 CFR 1.116–
EXPEDITED PROCEDURE EXAMINING
GROUP 1619 *

RESPONSE AND REQUEST FOR RECONSIDERATION

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

In response to the outstanding Official Action of June 20, 2001, reconsideration of the above-identified application is respectfully requested in view of the following remarks:

REQUEST FOR RECONSIDERATION

Claims 11-19 remain active in this application

The present invention is directed to a dispersion comprising particles of an amphipathic lipid dispersed in a surfactant and aqueous medium.

Amphipathic lipids such as ceramide are reported as components in hair and skin compositions. Formulations of such materials in an amount greater than 2 wt.% can be difficult due to the melting temperature of these materials. Attempts to address this problem by dissolving the ceramide and then emulsification have produced diminished effects.

Accordingly, compositions containing an amphipathic lipid at higher concentrations are sought.

The present invention addresses the problem by providing a **dispersion** of particles of an amphipathic lipid dispersed in a surfactant and aqueous medium in which the amphipathic lipid has **an average particle size of from 0.5 to 150 μm.** Applicants have discovered that particles of an amphipathic lipid may be dispersed in a surfactant and aqueous medium providing for increased concentrations of lipid while retaining the desirable effects. Such a dispersion of particles is nowhere disclosed or suggested in the prior art of record.

The rejection of Claims 11-19 under 35 U.S.C. §103(a) over Pillai et al, U.S. 5,476,661 in view of Vanlerberghe et al. U.S. 5,985,255 is respectfully traversed.

A composition in which particles of amphipathic lipid are dispersed in a surfactant and aqueous medium is nowhere disclosed or suggested in the cited prior art.

Pillai et al. reports a composition comprising 25-hydroxycholecalciferol, a lipid and a vehicle for the hydroxycholecalciferol and lipid. The reference **does not** describe the lipid component as **a dispersion** in surfactant and aqueous medium nor an **average particle size of 0.5 to 150 μm.** Quite simply there is no disclosure in the reference whatsoever of the physical state of the lipid in the composition and accordingly, there is certainly no description of particle size of the lipid. Moreover, there can be no suggestion of a dispersion of particles in a surfactant and aqueous medium, since there is no disclosure of particle whatsoever. Moreover, in Examples 4 and 6-11, the concentration of ceramide never exceeds 1.5 wt.%, consistent with Applicants' description on page 2, line 17 of the specification of the difficulties in formulating such compositions at high concentration of amphipathic lipid.

In contrast, the present invention is directed to a **dispersion** of amphipathic lipid particles dispersed in surfactant and an aqueous medium in **which the average particle size of the lipid is from 0.5 to 150 μm.** Applicants note that the claims recite that the amphipathic lipid is dispersed in the surfactant and aqueous medium.

In responding to Applicants' response of May 14, 2001, the examiner indicated that the term "dispersion " could not be given any patentable weight, since this term occurred in the preamble to the claim. Applicants respectfully note that the claim limitation of "a dispersion" appears in the body of the claim, *via* the use of the phase "dispersed in said surfactant and aqueous medium". As such the state of the particles as a dispersion is clear. Since the cited reference nowhere discloses or suggests such even a particle size for the lipid component, a dispersion of lipid particles in surfactant and aqueous medium is not suggested. Accordingly, the present invention is clearly not obvious from this reference and accordingly withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Vanlerberghe et al is directed to wax microemulsions in a liquid vehicle, have a particle size of less than 0.5 μm (column 2, lines 21-26).

A general teaching of perfume particle vehicles is found at column 1, lines 11-15, in which wax particles of between 0.1 to 200 μm are described as a vehicle for perfume. This reference teaches, that for a **perfume vehicle,** wax particles of between 0.1 to 200 μm are used. Accordingly the motivation provided by this reference to include wax particles of a size of from 0.1 to 200 μm is to serve as a perfume vehicle. The reference is silent as to the particle size of from 0.1 to 200 μm, of any components in a composition other than as a perfume vehicle. There is no motivation provided by this reference to formulate all components of a composition to a particle size of from 0.1 to 200 μm. Quite to the contrary,

the reference only teaches that, when formulating a composition containing a perfume, that wax particle of a size of from 0.1 to 200 μm are useful as a vehicle for perfume. Accordingly, the portion of Vanlerberghe et al. relied upon by the examiner, teaches only a perfume vehicle of a particle size of from 0.1 to 200 μm. Since the ceramide component of Pillai et al. is not a perfume vehicle, there is no motivation to formulate the ceramide component to a particle size of from 0.1 to 200 μm, much less the claimed particle size range of from 0.5 to 150 μm. The simple recitation of a particle size of from 0.1 to 200 μm for a perfume vehicle, in a reference which also describes a hair lotion does not provide motivation to formulate all components of the hair lotion to a particle size of from 0.1 to 200 μm.

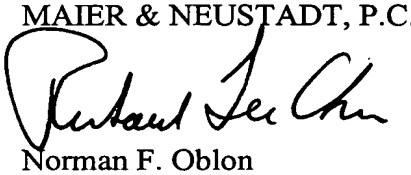
Regarding the more specific teachings of the reference and the formulation of a hair lotion (column 2, line 6) the reference only describes a composition of a "microdispersion" in which the particle size is less than 0.5 μm. There is no suggestion provided by this reference to formulate any component of a hair lotion to a particle size of from 0.5 to 150 μm. The reference only suggest formulation of a hair lotion comprising wax microdispersions of a particle size of less than 0.5 μm.

Since the secondary reference does not provide motivation to formulate all components of a hair lotion to a particle size of from 0.1 to 200 μm, the prior art relied upon by the examiner fails to disclose or suggest the claimed invention in which particles of from 0.5 to 150 μm are dispersed in a surfactant and an aqueous medium. This is a claim limitation which is not suggested by the cited references. Accordingly the claimed invention is clearly not obvious over the cited combination of references and accordingly withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Applicants submit that this application is now in condition for allowance and early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



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